PMUSA Clinical Evaluation Process:

Study Initiation Visit

Attachment: PMUSA Clinical Evaluation Study Initiation Visit

Issue Date and Number: 24 March. 2004 (1)

1. In order to assess the study site's and the investigator's ability to perform the clinical study, the Study Manager will schedule, organize, and conduct a study initiation visit approximately 2 to 4 weeks prior to the start of study conduct. In certain circumstances, this visit may be waived by the Director of Clinical Operations.

2. The Study Manager in conjunction with the Director of Clinical Operations will determine the required attendees.

3. The scope of the visit will include the agenda items listed in the attachment, as appropriate and applicable to the specific study and site.

Source: https://www.industrydocuments.ucsf.edu/docs/ngmj0001